K110112

APR 20 2011

510(k) SUMMARY
Dr. Li's MFA Syringe with Needle

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Rongshan Li, MD, Ph.D.
11 Georgetown Ct.
Basking Ridge, NJ 07920

Name of Device and Name/Address of Sponsor

Rongshan Li, MD, Ph.D.
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Common or Usual Names and Classification Names:

Common Names:	Piston Syringe	Hypodermic Needle	Biopsy Needle
Classification Name:	Piston Syringe	Hypodermic single lumen needle	Biopsy Instrument
Regulation:	880.5860	880.5570	21CFR876.1075
Class:	2	2	2
Product Codes:	FMF	FMI	KNW

Predicate Devices

The MFA Syringe with needle has the same intended use as the following predicate devices:

- Syringes and needles: DB Brand (K980580), Pentaferte® (K002381) and Terumo® (K083514)
- Biopsy needles: Bard Biopty-Cut (K962077) and Pan® (K970872)

Intended Use: The MFA Syringe with Needle is intended for use in aspirating a specimen of fluid or tissue out of the human body for pathologic examination.

Technological Characteristics and Substantial Equivalence:

The MFA and predicate devices have substantially similar technological characteristics in terms of design and materials. Although there are minor difference in the characteristics of the MFA device and its predicate devices, those differences do not raise new questions of safety or efficacy. MFA differs from some predicates in the range of syringe and needle sizes but is similar to those of other predicates. Compared with the predicates, the MFA Device has a different size and shape of the hub of the needle: the size of the hub is larger and has a larger lumen to allow the collected samples to be picked up and transferred to other containers. In

additional, the inner end of the needle that is located in the lumen of the hub has a cover above the opening of the needle to prohibit the collected sample getting up into the lumen of the syringe. In order to test the function of the cover, a non-clinical Device Function Test was performed using different animal organs and tissues to compare MFA device and predicate devices in a manner of mimicking a procedure in human projects. The test demonstrates that the larger capacity of the hub and the cover of the needle in the MFA devices significantly prevented the fluid from spreading into the lumen of the syringe in cases where more than 50 μl of liquid samples were collected when compared with the predicate devices, and the larger capacity of the hub and the cover of the needle in the MFA devices significantly prevented the collected solid tissue samples from spreading into the lumen of the syringe when compared with the predicate devices. The part of the needle that will penetrate the skin into the body is the same as that of predicate devices; therefore there is no additional risk of the MFA for patients when compared with the predicates. The MFA device aspirates fluid and tissue samples from the human body in a manner equivalent to that used by the predicate devices. *In vitro* diagnostic tests are **NOT** part of this needle/syringe 510(k) application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Rongshan Li, MD, Ph.D.
11 Georgetown Court
Basking Ridge, New Jersey 07920

APR 2 0 2011

Re: K110112
Trade/Device Name: Multifunction Aspiration (MFA) Syringe with Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, FMF, FMI
Dated: April 11, 2011
Received: April 11, 2011

Dear Dr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment J

Indications for Use Statement

510(k) Number (if known): Not available

Device Name: MFA Syringe with Needle

Indications for Use:

The MFA Syringe/Needle Device is a syringe with needle intended for use in aspirating a specimen of fluid or tissue out of the human body for pathologic examination.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NECESSARY0

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number_____

Prescription Use__X___ or Over-The-Counter Use_____
(Optional Format 1-2

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110112